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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,735	02/11/2002	Anne Chew	MWH-0007US	4233

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GENAISSANCE PHARMACEUTICALS
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NEW HAVEN, CT 06511

EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/073,735	CHEW ET AL.	
	Examiner	Art Unit	
	Jeanine A. Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.2.0.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to methods of haplotyping and genotyping FCER1A, classified in class 435, subclass 6.

II. Claims 8-9, drawn to methods of assigning haplotype pairs, classified in class 702, subclass 19.

III. Claim 10-11, drawn to methods of associating a phenotype and a haplotype, classified in class 436, subclass 501.

IV. Claims 12-19, 22-23, 26, 32 drawn to nucleic acids, classified in class 536, subclass 23.1 and 24.3.

V. Claims 20-21, 24-25 drawn to recombinant nonhuman organisms, classified in class 800, subclass 8.

VI. Claim 27, 30 drawn to a polypeptide, classified in class 530, subclass 350.

VII. Claim 28, drawn to an antibody, classified in class 530, subclass 387.1.

VIII. Claim 29, drawn to method of drug screening using a polypeptide, classified in class 436, subclass 501.

IX. Claim 31, drawn to a computer system, classified in class 711, subclass 100.

2. The inventions are distinct, each from the other because of the following reasons:

A) Inventions in Group I, Group II, Group III, Group VIII are distinct because the Inventions in these groups have different modes of operation, different functions, or different effects. In particular, the haplotyping method of Group I has different functions and effects from the other methods since it operates by determining sets of polymorphisms in their relationship to one another on single chromosomal strands and results in the identification of haplotypes or strings of single nucleotide polymorphisms which may be present in particular populations. The haplotyping methods of require steps of identifying haplotypes and haplotype pairs to achieve the objectives of haplotyping. The method of predicting haplotype pairs of Group II differs from Group I in that it functions to identify actual information present in populations regarding two different haplotypes, rather than simply. The predictive methods require steps of identifying two polymorphisms in a gene to achieve the objective of "predicting a haplotype pair". The method of associating a phenotype with a haplotype is distinct from the previous groups because it requires determination of information about populations and the correlation of that information with haplotypes. Thus, the association methods requires steps of comparing frequencies of haplotypes in a population to achieve the objective of "identifying an association between a trait" and a haplotye. The ligand screening methods of Group VIII require steps of assaying for binding activity for candidate agents. Each of these groups has results and steps different from each other group.

B) Inventions in Group IV, V, VI, VII, and IX are distinct because the Inventions in these groups have different modes of operation, different functions, or different effects. The polynucleotides, kits, and various compositions, recombinant organisms,

polypeptides, antibodies, computer system, and genome anthologies are additionally drawn to multiple, distinct products lacking the same or corresponding special technical features. The nucleic acids are composed of nucleotides and function in , e.g., methods of nucleic acid hybridization or amplification. These groups are directed to different combinations of nucleic acids which are different from one another and may be employed in different methods. The recombinant organisms are complex organisms that are employed in, e.g. animal research methods. Such organisms cannot be employed as, e.g., probes or primers and they differ in both structure and function from the nucleic acids. The polypeptides differ in both structure and function from either the nucleic acids or the transgenic organisms. The polypeptides are composed of amino acids linked by peptide bonds and arranged in a complex combination of alpha helices, beta pleated sheets, hydrophobic and hydrophilic domains. The polypeptides also differ in function, e.g., fusion proteins with an enzymatic functions. The antibodies are composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. The antibodies function in immunoassays. Further the computer systems are composed of, e.g., a CPU, a display device, an input device, etc., and function in, e.g., methods of electronic sequence comparison. Accordingly, the products of each of these Groups differ structurally and functionally from each other. As products of different sets of Groups differ from each other in structure, function, and effect, they do not belong to a recognized class of chemical compound, or

have both a "common property or activity" and a common structure and are therefore properly distinct inventions.

C) Inventions in Group IV and in Groups I-III, IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid products can be used for the diagnostic methods of Group I-III, IX for PCR amplification methods, for nucleic acid purification methods or for antisense treatment methods.

D) Inventions in Groups VI and VII and in Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the proteins and antibodies of Groups VI and VII can be used in the drug screening method of Group VIII, in purification methods, or in protein activity assays.

Restriction Requirement Applicable to All Groups:

6. This application contains claims directed to the following patentably distinct Inventions of the claimed invention. These subgroups are independent and distinct because each polymorphic site and each molecule containing said polymorphic site is structurally and functionally distinct from each other polymorphic site and molecules

containing said site. The chemical structure of each polymorphism and of each molecule containing the same differ from each other. For example, a polynucleotide comprising PS1 is chemically, structurally, and functionally different from a molecule comprising PS3. Further, with particular respect to the haplotype and genotyping claims, it is noted that the haplotypes and genotypes encompassed by these claims are also distinct from each other and from the single polymorphisms recited. For example, a molecule of haplotype 1, comprising a particular combination of polymorphisms, differs chemically, structurally, and functionally from a molecule of haplotype 2 and from a molecule comprising a single polymorphism (e.g., PS1).

7. In order to be perfectly clear, the following Inventions within the particular Groups are **NOT** species elections. These are independent and distinct Inventions for the reasons given above and a further election of a single Invention from the elected Group is required.

8. Further restriction is required as follows:

Upon election of **group I**, applicant should further elect

(a) a single haplotype

(b) a single haplotype pair comprising that haplotype

(c) a single combination of polymorphisms to be examined for claims 3 and 5.

Upon election of **group II**, applicant should further elect a single combination of polymorphisms to be identified in the method.

Upon election of **group III**, applicant should further elect a single haplotype.

Upon election of **group IV** applicant should further elect

(a) a single isogene

(b) a single set of polymorphic sites as listed in claim 13 that the fragment must comprise (Applicant should identify whether this set of sites includes the one referred to in claim 16, if not, claim 16 will be withdrawn from prosecution.)

(c) a single polymorphic site as listed in claim 23. This polymorphic site must be within the group selected for (b) (Applicant should identify whether this site is the same as the one referred to in claim 16, if not, claim 16 will be withdrawn from prosecution.) Applicant should further identify the appropriate SEQ ID NO that correspond with this site.

(d) A single group of isogenes to be contained in the genome anthology. These should include the isogene of (a).

Upon election of **group V** applicant should further elect

(a) a single isogene.

Upon election of **group VI, VII, VIII, IX, X, or XI** no further election is required.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches for each Group would be divergent from each other Group, so restriction for examination purposes as indicated is proper.

4. With regard to the different Inventions, the burden of search exists because a different search is required for each separate PS site, haplotype and molecule. For example, in order to properly search PS1, this haplotype will need to be searched in the Registry file of STN, in the computer database maintained by the STIC and will also require individualized searching in papers which disclose polymorphisms in the FCER1A gene. Each paper may need to be separately reviewed. Potentially, any of these papers could be relevant to the claimed invention. Review of this information would be different for each PS site, haplotype and molecule and would be burdensome.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 6:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg
Primary Examiner
May 19, 2005